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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,575	11/16/2001	Johann Eibl	A34720-PCT-USA-A	7871

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BAKER BOTTS L.L.P.  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER
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WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/998,575	<b>Applicant(s)</b> EIBL, JOHANN	
	<b>Examiner</b> Jon P Weber, Ph.D.	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-130 is/are pending in the application.
- 4a) Of the above claim(s) 3-98 and 105-130 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 99-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/16/01,6/10/00</u> | 6) <input type="checkbox"/> Other: _____  |

*Status of the Claims*

Claims 1-107 have been presented for examination.

*Election/Restrictions*

Applicant's election without traverse of group I, claims 1-104, and the species A) structural proteins, and (B) allogenic collagens as the structural proteins **with** traverse in the Paper filed 02 January 2004 is acknowledged. Claims 105-107 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election of the Group was made **without** traverse. It is suggested that the non-elected claims be canceled in response to this Office action to expedite prosecution.

In traversing the species election it is argued that the species are additional components not required for claim 1, and as such, applicants should not be limited in examination of additional components.

The additional components are active ingredients that would materially affect the basic and novel characteristics of the claimed invention. Accordingly, it is proper to consider that searching each and every one of the added active ingredients could entail burden. Burden is established because each of these possible ingredients requires a separate search inasmuch as the different active ingredients are not classified together or recognized in the art as being coextensive. It is noted that examiner could have, but did not, require a species election on claim 1 element (iv) "serpins" although there are at least 219 such polypeptides known in the art (Irving et al., 2000) having a wide range of names and diverse structures and properties.

Claims 105-107 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim.

Election was made **without** traverse in the Paper filed 02 January 2004.

Claims 3-98 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim (*vide infra*). Applicant timely traversed the restriction (election) requirement in the Paper filed 02 January 2004.

Claims 1-2 and 99-104 remain to be examined on the merits

#### ***Claim Rejections - 35 USC § 112***

Claims 1-2 and 99-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the active agents “may be obtained” which is vague and indefinite because it is not clear if the group of sources is a required claim element or only a suggestion of possible sources that may also include essentially any other source.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 99-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wadström et al. (US 5,631,011) and Redl et al. (CA 2302224) and Edwardson et al. (US 5,739,288).

Wadström et al. (US 5,631,011) disclose using fibrin or fibrinogen in a sealant comprising thrombin, transglutaminase (factor XIII), and fibrinolysis inhibitors such as  $\alpha$ 1-antitrypsin, PAI-1 or PAI-2, instantly preferred serpins lacking elastase or collagenase activity (column 4, lines 46-65) in combination with additional biofibers such as collagen (column 5, line 61). Wadström et al. (US 5,631,011) lacks autologous sources for the active ingredients or collagen.

Redl et al. (CA 2302224) disclose a fibrinogen-based tissue adhesive/sealant comprising fibrinogen, thrombin (added just before use, Example 1), serum transglutaminase (Factor XIII) and a fibrinolysis inhibitor. The preferred fibrinolysis inhibitor is an elastase inhibitor. The adhesive/sealant may comprise many other added active ingredients including but not limited to collagen (page 12). Any source of the active ingredients is acceptable. Redl et al. (CA 2302224) lacks serpins lacking elastase or collagenase activity as the fibrinolytic inhibitor, autologous sources for the active ingredients or collagen, or fibrin as the other sealant agent.

Edwardson et al. (US 5,739,288) disclose the use of non-crosslinked fibrin in a fibrin-based adhesive/sealant. The blood used to make the fibrin sealant may be autologous (column 5, lines 7-8). It is also reported that it is known in the art to add fibrinolytic inhibitors such as PAI-1 or PAI-2 (the instantly most preferred serpins) to the fibrin sealant (column 23, lines 14-15).

A person of ordinary skill in the art at the time the invention was made would have been motivated to substitute autologous sources for the active components of the fibrin

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adhesive/sealant of Wadström et al. (US 5,631,011) and Redl et al. (CA 2302224) because Edwardson et al. (US 5,739,288) disclose them to be functionally equivalent in a fibrin adhesive or sealant save the well-known advantage of eliminating an immunological reaction. Wadström et al. (US 5,631,011) and Edwardson et al. (US 5,739,288) both disclose that the fibrinolytic inhibitors are readily selected from a small group that highlights the most preferred serpins of the instant application.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use autologous active ingredients, fibrin or fibrinogen, or serpins lacking collagenase or elastase activity in a fibrin-based adhesive/sealant.

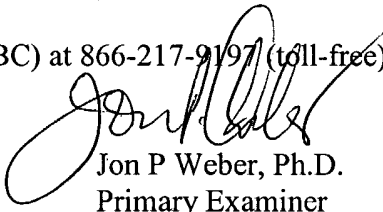
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW

9 March 2004